Evonik Operations GmbH - D-63403 Hanau

Evonik India Private Limited.
B5 & B6 Arham Logiparc,
Nashik Mumbai By Pass Road,
421302 VALSHIND, BHIWANDI, THANE
INDIA

Inspection Certificate 3.1 according to EN 10204	
Date	08.06.2021
Delivery Number / Item	3007316435 / 900010
Order Number / Item	46218415 / 000010
Silica	
Customer no.	502840

Sold-to
Evonik India Private Limited.
B5 & B6 Arham Logiparc,
Nashik Mumbai By Pass Road,
421302 VALSHIND, BHIWANDI, THANE
INDIA

Product	AEROSIL® 200 Pharma 18 x 10 KG / 22.00 lbs Paper Bag - / CP3 pallet heat treated
Material	99034594
Quantity	3.600 KG = 360 BAG
Batch	151050714
Production date	07-May-21
Expiration date	06-May-23
Delivery date	08-Jun-21
Spec.No.	K00, Vers. 01.12.2020
Container/Railcar	UACU 846314-3
Seal Text	K 263626

Delivery date = Estimated time of dispatch / departure

Property	Test method	Unit	Value	Target	Min.	Max.
Specific surface area	ISO 9277, modified	m^2/g	201	200	175	225
Identification	tested acc. to Ph.Eur.		Conforms	pass		
Assay (SiO2 content)	tested acc. to Ph.Eur.	%	100.2		99.0	100.5
pH value	tested acc. to Ph.Eur.		4.3		3.5	5.5
Chlorides <=250ppm	tested acc. to Ph.Eur.		Conforms	pass		
Loss on ignition	tested acc. to Ph.Eur.	%	0.3			5.0
Identification (1),(2) and (3)	tested acc. to JP		Conforms	pass		
Loss on drying	tested acc. to JP	%	0.3			7.0
Loss on ignition	tested acc. to JP	%	0.5			12.0
Al content	tested acc. to JP		Conforms	pass		

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Material	99034594	Date	08.06.2021
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Property	Test method	Unit	Value	Target	Min.	Max.
Fe content <=500ppm	tested acc. to JP		Conforms	pass		
Ca content	tested acc. to JP		Conforms	pass		
As content <=5ppm	tested acc. to JP		Conforms	pass		
Cl content <=0,011%	tested acc. to JP		Conforms	pass		
Heavy metals <=40ppm	tested acc. to JP		Conforms	pass		
Assay (SiO2 content)	tested acc. to JP	%	99.3		98.0	
As content <=8ppm	tested acc. to USP/NF		Conforms	pass		
Loss on drying	tested acc. to USP/NF	%	0.2			2.5
Loss on ignition	tested acc. to USP/NF	%	0.3			2.0
Identification, A and B	tested acc. to USP/NF		Conforms	pass		
pH value	tested acc. to USP/NF		4.1		3.5	5.5
Assay (SiO2 content)	tested acc. to USP/NF	%	100.0		99.0	100.5
As content (E551)	SOP AE_FQ01	ppm	Conforms			3.0
Pb content (E551)	SOP AE_FQ02	ppm	Conforms			5.0
Hg content (E551)	SOP AE_FQ03	ppm	Conforms			1.0
Na2SO4 content (E551)	SOP AE_FQ06	%	Conforms			5.0
Identification	tested acc. to IP		Conforms	pass		
Assay (SiO2 content)	tested acc. to IP	%	100.2		99.0	100.5
pH value	tested acc. to IP		4.3		3.5	5.5
Loss on ignition	tested acc. to IP	%	0.3			5.0
As content <=8ppm	tested acc. to IP		Conforms	pass		
Heavy metals <=25ppm	tested acc. to IP		Conforms	pass		
Chlorides <=250ppm	tested acc. to IP		Conforms	pass		

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AEROSIL® 200 Pharma:

Colloidal Silicon Dioxide tested according to Ph.Eur., USP/NF, JP and IP (current Version).

TAMC (total aerobic microbial count) , TYMC (total combined yeast and mould count) and Gram-negative bacteria are tested on a regular basis acc. to USP .

Manufactured and packaged in a dedicated closed production system according to GMP guidelines established for bulk pharmaceutical excipients by the International Pharmaceutical Excipients Council (IPEC/GMP).

Material manufactured applying an HACCP system which fulfills the requirements of the following regulation of the European Union: (EC) No 852/2004.
Purity criteria for E 551 according to (EU) 231/2012 (specifications for food additives regarding (EG) 1333/2008 Annex II and III) are met.

White, fine, amorphous powder.

Typical sieve residue (Grit, 45 µm) is < 0.025 % (according to ISO 787-18).

Elemental Impurities:
Elemental Impurities are not intentionally added to the production process.
The elemental impurities of the ICH Q3D are tested on a regular basis acc. to USP 233 and Ph. Eur. 5.20.

Residual solvents:
No organic solvents are used in the manufacture of above mentioned product. For this reason, constitutionally no residual solvents as cited in recent versions of the European Pharmacopoeia, (class 1, 2 and 3 or other solvents, USP chapter 467), 2008 and amendments are present in concentration about the control limits quoted in USP. For above mentioned product class 1 residual solvents are tested on a regular basis according to USP/NF: Carbon tetrachloride, 1,2 Dichlorethane, 1,1 Dichlorethene, 1,1,1 Trichlorethane and Benzene.

TSE/BSE and materials of plant origin:
No raw materials of animal or plant origin (as mentioned in EMEA/410/01, current version) are used in the production process of AEROSIL® Pharma products. AEROSIL® Pharma products have not been in contact with and constitutionally do not include any material of animal or plant origin. We generally do not use any material of animal or plant origin in our production facilities. AEROSIL® Pharma products are not contaminated with material of animal or plant origin when they leave our production and warehouses.

This product is manufactured in Site'Rheinfelden, Untere Kanalstrasse 3, 79618 Rheinfelden, Germany.

Dr. Martina Altemöller
Inspector
Rheinfelden site
Untere Kanalstraße 3, 79618 Rheinfelden, Germany
+49 7623 917252
RHE-QM-AE@evonik.com

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*** End ***

Evonik Operations GmbH
Rellinghauser Str. 1-11
45128 Essen
Germany

Tel.: +49 201 177-01
Fax: +49 201 177-3475
www.evonik.com